

Serial No.: 10/047,079  
 Group Art Unit: 3762  
 Examiner: L. Deak  
 Atty. Docket No.: 22719-26

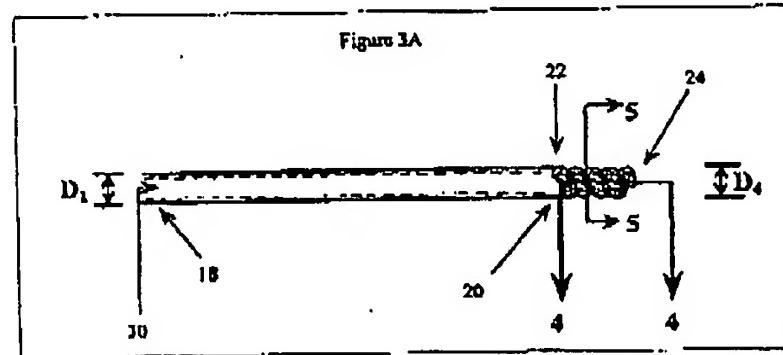
## REMARKS

The present Office Action addresses and rejects claims 3 and 5-20.

Claims 3 and 5-20 are rejected pursuant to 35 U.S.C. §103(a) as being obvious over U.S. Patent No. 5,141,502 of Macaluso, Jr. ("Macaluso") in view of U.S. patent No. 5,514,176 of Bosley, Jr. ("Bosley"). The Examiner argues that Macaluso discloses a catheter substantially as claimed, except the diameter of the coiled region being dimensioned to fit within a deployment catheter. Thus, the Examiner relies on Bosley to disclose a coiled stent having a spiral distal tubular region that fits in a catheter for deployment into a body in order to prevent tissue growth between the coils. The Examiner argues that "it would have been obvious to one of ordinary skill in the art at the time of [the] invention to form the coils of the Macaluso device in a manner that [would allow the device to] fit within a deployment catheter for ease of insertion and removal, as disclosed by [sic] Bosley." (March 9, 2005 Office Action, page 3.)

The Examiner has apparently disregarded the language of the claims, as none of the claims require the use of any type of deployment catheter, much less a catheter having a coiled region with a diameter that is dimensioned to fit within a deployment catheter.

Independent claim 3 recites a fluid management device having a catheter with a coil-shaped distal portion that has an outer diameter, measured across the coil, that is substantially equal to an outer diameter of a proximal portion of the catheter. This is illustrated in Figure 3A of the present application, which is reproduced herein for the Examiner's convenience. As shown,  $D_4$  refers to the diameter of the coil-shaped region, which is substantially equal to  $D_1$ , which is the diameter of the proximal portion of the catheter. Such a configuration is particularly effective for use in treating hydrocephalus, where the diameter of the catheter must remain relatively small "to minimize the damage that may result during implantation of the fluid management device." (Pending Application, page 8, lines 17-18.) The prior art references

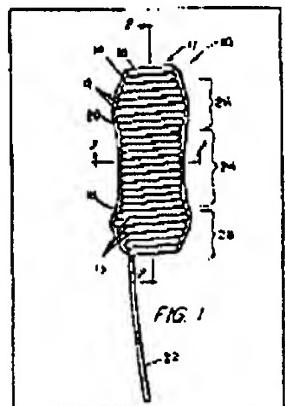
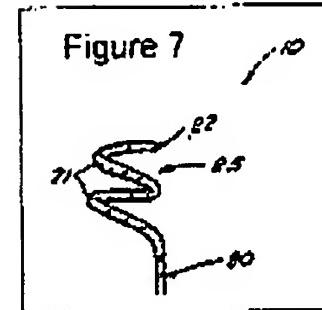


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do not teach or even suggest the claimed fluid management device.

As previously discussed in Applicant's Amendment and Response filed on November 1, 2004, Macaluso discloses a catheter having a helix (21) with an outer diameter that is significantly greater than an outer diameter of the catheter. The catheter of Macaluso is shown in Figure 7, which is reproduced herein. As is clearly shown, Macaluso does not teach or even suggest a catheter having a coiled distal portion with an outer diameter that is substantially equal to an outer diameter of a proximal portion of the catheter. In fact, since the diameter of the catheter is constant along the entire length of the catheter, the diameter of the coiled distal portion necessarily must be larger than the diameter of the proximal portion, regardless of how tightly wound the coiled region may be.



Bosley does not remedy the deficiencies of Macaluso, as Bosley likewise fails to teach or even suggest a catheter having a coiled distal portion with an outer diameter that is substantially equal to an outer diameter of a proximal portion of the catheter. Figure 1 of Bosley is reproduced herein, and as shown the distal portion, like Macaluso, has an outer diameter that is significantly larger than the diameter of the proximal portion. As noted above with Macaluso, the diameter of the coiled region would necessarily be larger than the diameter of the proximal portion, regardless of how tightly wound the coiled region may be, since the catheter itself has a constant diameter along the length thereof.

Accordingly, independent claim 3 distinguishes over the cited references and represents allowable subject matter. Claims 5-18 are allowable at least because they depend from an allowable base claim.

Independent claim 19 also distinguishes over Macaluso and Bosley. Claim 19 requires a coil-shaped region having successive turns that are spaced apart from one another by a distance that is *adapted to prevent tissue from growing into the coil-shaped region*. None of the

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references teach or even suggest such a configuration.

As shown in Figure 7 of Macaluso above, the coiled region has successive turns that are significantly spaced apart from one another. The shape of the coil is specifically designed to fit within a patient's bladder. Due to the significant spacing, the coil-shaped region is *not* adapted prevent tissue from growing therein, as required by independent claim 19.

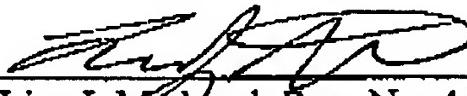
Bosley does not remedy the deficiencies of Macaluso. As shown in Figure 1 of Bosley above, the catheter includes a coil-shaped region formed by multiple coil loops. The coil loops are *secured* to one another during curing, or using an adhesive or other securing means. Thus the coil loops are not spaced apart from one another, as required by independent claim 19.

Accordingly, independent claim 19 distinguishes over the cited references and represents allowable subject matter. Claim 20 is allowable at least because it depends from an allowable base claim.

#### *Conclusion*

Applicants submit that claims 3 and 5-20 are in condition for allowance, and allowance thereof is respectfully requested. Applicants encourage the Examiner to telephone the undersigned upon receipt of this response to discuss any issues that may remain.

Respectfully submitted,

  
Lisa J. Michaud, Reg. No. 44,238  
Attorney for Applicant(s)

NUTTER, MCCLENNEN & FISH, LLP  
World Trade Center West  
155 Seaport Boulevard  
Boston, MA 02210-2604  
Tel: (617)439-2550  
Fax: (617)310-9550

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